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EXAMINER

LAURITZEN, AMANDA L

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/713,637	Applicant(s) DUNKI-JACOBS ET AL.	
	Examiner A. LAURITZEN	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 5-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

This action is in response to communications filed 21 December 2007. Amendment(s) to claim 28 are interpreted to introduce new matter, as it is not clearly disclosed that the display indicates the target tissue type detected. New grounds of rejection under the first paragraph of 35 U.S.C. 112 are presented herein.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive and/or are moot in view of new grounds of rejection.

Regarding claims 12-27 in view of Kovacs et al. (US 5,833,603), the rejection is in fact an obviousness rejection under 103(a), contrary to applicant's assertion that Examiner relied on the reference to anticipate the claimed invention. The variation between the disclosure of Kovacs et al. and the claims was presented alongside a rationale that would motivate one of ordinary skill in the art to modify the invention. For example, for detectors disposed oppositely within the capsule as in claim 1, since this feature presents no novel or unexpected result over the detector layout disclosed in both the Kovacs and Okada et al. references, and solves no stated problem, it is considered an obvious matter of design choice within the skill of the art (p. 5 of non-final Office action of 24 September 2007). This conclusion is valid because applicant's disclosure of the invention does not cite any criticality for disposing the detectors at opposite ends of the capsule. It is maintained that disposing detectors oppositely is obvious within the skill of the art because the arrangement yields the expected result of targeting more of the surrounding tissue as the detectors will be oriented in opposed directions, for detection from both ends of a capsulated device. This teaching is well known within the art and, to demonstrate, Examiner points to Mizuno (US 2005/0250991) for disclosing imaging detectors (broadly

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encompassed by the claimed “detectors”) that are disposed at opposite end portions of a capsulated device [0057] to achieve this expected result.

Applicant has pointed to paragraph [0079] of the specification alongside the allegation that the “positioning of the detectors provides a directional response that is largely insensitive to broad background sources, ” which is not found in the paragraph specified, nor in anywhere else within applicant’s specification, specifically in conjunction with prescribing the detectors at opposite end portions of the capsule. Instead, this feature of oppositely disposing the capsules is introduced at [0075] as an alternative or optional arrangement. The feature of being insensitive to background sources is not linked specifically with this arrangement.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 28-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 28, as amended, recites providing a display that “indicates the detection of the target tissue *type...*”. The features of the display prescribed in the claim are best corresponded to Figs. 8 and 9 (paragraph [0112]), in which a signal is presented with respect to the position of the

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capsule along the GI tract, as claimed, but it is not specifically detailed in the specification that the display will indicate to the user the target tissue type.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 12-27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2 and 4-20 of copending Application No. 10/713407. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim sets are directed to a method for detecting target cells and delineate substantially similar steps of marking target cells and directing a detector through a patient's GI tract. The conflicting claims are more specific and therefore anticipate the instant claims. The step of “differentiating between signals associated with target cells of the particular

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cell type...” of conflicting claims 1 and 2 is anticipatory because it can be used for detection of cancerous tissue.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 12-27 and 28-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 3 of copending Application No. 10/713407. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim sets are directed to a method for detecting target cells in a patient, with the binding of step (a) of conflicting claim 3 being analogous to “having an affinity for” as in current claim 28. The instant claims are broader and are therefore anticipated by the conflicting claim. The instant claims are broader in that they do not specify administration of a clearing agent. The steps of tracking the position of the detector along the GI tract and displaying the target cell type in relation to the position of the detector along the GI tract are substantially similar to claim 28.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 12-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kovacs et al. (US 5,833,603) in view of Adair et al. (US 6,750,037) and Iddan et al. (US 5,604,531).

Kovacs et al. disclose a system and method for detecting tissues comprising an encapsulated detector and administering a substance for associating with (or marking) a target tissue, the substance being capable of being detected by the detector for determining the presence or levels of specific chemicals within a patient and “sensing physical parameter values directly related to the patient’s organs and tissues” (col. 1, line 65; also col. 3, lines 10-33; col. 4, lines 45-49). The signals detected are mathematically analyzed to determine whether a particular tissue is present in the patient, examples being temporary implants, prostheses, patient organs, and tissues (col. 3, lines 24-32).

Regarding claims 13-18, Kovacs et al. further disclose method steps of verifying at least one component and concentration (amount of chemical or biochemical substance) of the physical properties of the tissue, cell, and biochemical components of a region of interest. While Kovacs et al. do not explicitly state that the detection substance is a monoclonal body, peptide, nanoparticle, mRNA and DNA corresponding to a generic monoclonal antibody, and liposome, these are inherent properties of biochemical composition of the tissues and cells (col. 6, lines 26-36). In addition, Kovacs et al. disclose that the biosensor detects energy spectra via an optical or photo-sensing element, which is used along with the dye to acquire optical radiation. Although Kovacs et al. do not explicitly recite use of radioisotopes, the dye solution with radiation optical acquisition it is inherent that the dye solution be radioactive or a radioisotope (col. 1, lines 56-65; col. 4, lines 34-44; col. 5, lines 5-26. Further, Kovacs et al. disclose the method above where the sensor is a spectrophotometer acquiring multiple images of data from a region of interest with predetermined spectrum, wavelengths and position to detect optical spectrum (i.e., a spatial response pattern at col. 1, line 66 - col. 2, line 11).

It is known in the art that cancer cells are known to have a higher affinity for certain positron-emitting radioactive substances; however, the feature of detecting whether cancerous tissue is present is not specifically disclosed in Kovacs et al. In the same field of endeavor, Adair et al. teach a method of cancer screening including introducing a compound to a patient for cell uptake, wherein cancerous cells have a natural affinity for the compound. The compound has a fluorescent marker associated therewith and a radioisotope which creates a radioactive maker in targeted cells (col. 18, lines 45-53). It would have been obvious to one skilled in the art at the time of invention to have incorporated the teaching of Adair et al. to enable specific binding to cancerous cells for improved detection.

Neither Adair nor Kovacs et al. specifically address a capsule traversing through the GI tract of a patient, but this deficiency is accounted for in Iddan et al., in which a capsulated detector is disclosed. The capsule of Iddan et al. is swallowable and coated with material to allow the detector to pass through the GI tract. In addition, a reception system 12 is used with the data processor 14 and position monitor 16 for tracking the position of the detector along the GI tract (col. 1, lines 43-40; col. 3, line 8 - col. 5, line 6). It would have been obvious to one ordinarily skilled in the art at the time of invention to apply the teachings of Iddan et al. such that the device is swallowable and traverses the GI tract.

5. Claims 1, 5-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kovacs et al. '603 in view of Iddan et al. (US 5,604,531) and Okada et al. (US 5,424,546).

Kovacs et al. disclose a system for detecting tissues comprising a capsule comprising a detector, a substance for associating with a target tissue where the substance is capable of being detected by the detector and a machine for verifying at least one of the detector and substance are

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suitable for use (col. 3, line 10 – col. 4, line 59; col. 6, lines 8-56). In addition, Kovacs et al. disclose that the capsule includes multiple detectors, a radiation detector, magnetic detector, and single analyzer for each detector (col. 4, lines 35-44). Although Kovacs et al. disclose implantation of the sensor device, Kovacs et al do not disclose that the capsule is a swallowable or that the capsule material is coated to allow the capsule to pass through the gastro-intestinal (GI) tract. However, Iddan et al. teaches a similar capsule detector where the device is swallowable and coated with material to allow the detector to pass through the GI tract (col. 1, lines 34-40; col. 3, line 8 – col. 5, line 6). In addition, neither Kovacs et al. nor Iddan et al. specifically disclose that detector pulse shaping device is in direct communication with a single channel analyzer configured to analyze the voltage output; however, Okada et al. teach an endoscope or catheter with a detector includes single channel analyzer that counts the detected photons, i.e. voltage output from the pulse shaping device (col. 10, lines 13-29). Iddan et al., at col. 3, lines 32-33, teach a detector disposed within a capsule. Okada et al. disclose two radiation detectors, pulse-shaping circuits and a single-channel analyzer at col. 10, lines 13-29, and establish that this technology is known within the art of performing photon counting operations for an organism injected (i.e., marked) with a radioactive substance (col. 1, lines 19-22). The components of Okada et al. could be encapsulated and coated for ease of transfer through the GI tract (as taught by Iddan et al. at col. 1, lines 34-40; col. 3, line 8 – col. 5, line 6). It would have been obvious to modify the device of Kovacs et al. to be swallowable and coated as taught by Iddan et al. in order to enable natural progression through the GI tract, and to further modify to include the pulse-shaping circuits and single channel analyzer of the probe of Okada et

al. for the purpose of measuring the concentration of radiation in a certain area of an object or organism treated with a radioactive substance (col. 1, lines 19-22; 26-27).

Both Okada et al. and Kovacs et al. disclose multiple detectors and/or an arrangement with two radiation detectors, but neither is specific to the detectors being disposed at opposite ends of the capsule; however, this feature presents no novel or unexpected result over the detector layout disclosed in the references. Disposing detectors oppositely in lieu of the arrangements disclosed in either Okada or Kovacs et al. solves no stated problem and is therefore considered an obvious matter of design choice within the skill of the art.

6. Claims 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kovacs et al. '603 in view of Iddan et al. (US 5,604,531) and Okada et al. (US 5,424,546)

Regarding claim 28, the substance associated with the particular tissue that is detected can be taken either as the dye marking substance as in Kovacs et al. or the radioactive marking substance as in Okada et al. The "target tissue" or "particular tissue" as recited in the claims are interpreted to encompass any desired tissue of interest. Okada et al. cites "detecting the distribution of radiation" in an organism (col. 2, lines 7-8). Different tissue types will naturally have varying affinity for radioactive substances and likewise, the distribution of radiation will depend on that affinity, and it is additionally known within the art that cancerous cells will have a higher affinity for certain positron-emitting radioactive substances. Therefore a measure of the distribution of radiation will correspond to target tissue distribution and the presence of target tissues with a high affinity for radiation will be identifiable.

The capsule of Iddan et al. is swallowable and coated with material to allow the detector to pass through the GI tract. In addition, a reception system 12 is used with the data processor 14

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and position monitor 16 for tracking the position of the detector along the GI tract (col. 1, lines 43-40; col. 3, line 8 - col. 5, line 6). It would have been obvious to one ordinarily skilled in the art at the time of invention to apply the teachings of Iddan et al. such that the device is swallowable, traverses the GI tract, and can be accurately monitored with position display.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. LAURITZEN whose telephone number is (571)272-4303. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. L./
Examiner, Art Unit 3737

/Brian L Casler/
Supervisory Patent Examiner, Art Unit
3737